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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert J. LEVY *et al.*

Title: METHODS AND COMPOSITIONS FOR ENHANCING THE DELIVERY OF A NUCLEIC ACID TO A CELL

Appl. No.: 09/851,327

Filing Date: May 9, 2001

Examiner: Scott D. PRIEBE

Art Unit: 1632

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This communication responds to the office action dated September 25, 2002, concerning the above-referenced patent application. Although applicants believe that no fee is due, the Commissioner is hereby authorized to charge any deficiency to Deposit Account No. 19-0741, including any extension of time, and to treat this authorization as a petition for any extension of time determined to be necessary for this response to be considered timely.

In the office actions dated August 22 and September 25, 2002, the examiner restricted the claims into the following two groups:

> Group A, claims 1-33, drawn to delivery of a nucleic acid which encodes a product; and
>
> Group B, claims 1-33, drawn to delivery of antisense or ribozyme nucleic acid.

The examiner further restricted each group A and B into 25 separate groups (A1-A25 and B1-B25), asserting that "each invention is directed to the use of a particular 'agent'" and that "the particular 'agent'...distinguishes each invention from the others" (Paper No. 5 at 2).

Applicants provisionally elect Group A3, with traverse, because the alleged separate inventions in fact are related and should be examined together. In particular, the agents listed in groups A3, A7-A23 and A25 are all intermediates in the Tenacin C (TN-C) and TB4 receptor signaling pathway. Denatured collagen (group A2) also is related, in that it is a Tenacin C-inducing substrate; that is, it provokes expression and extracellular deposition of Tenacin C.

The examiner has grouped Tenacin C and TB4, applicants understand, because the up-regulation of Tenacin C results in up-regulation of the expression of TB4. By the examiner's rationale, it would only make sense to include the agents listed in A7-A23 and A25, since they likewise are intermediates involved in the up-regulation of TB4. (See Figure 5 in the instant application, which is a schematic of the TN-C and TB4 pathway.)

Furthermore, the examiner asserted that "[e]ach of the inventions of A1-A25 or B1-B25 [is] directed [to] different agents which lead to a common effect – enhancing cytoskeletal permissiveness" and that "each agent...achieves the common effect by a different mechanism" (Paper No. 5 at 5). Applicants respectfully disagree. Each of the agents listed in A1-A25 enhance cytoskeletal permissiveness by enhancing the level of G-actin, whether it be by increasing depolymerization of F-actin, rendering G-actin less susceptible to proteolysis, up-regulation of TB4, etc. Moreover, each of the agents listed in A2, A3, A7-A23 and A25 not only enhances cytoskeletal permissiveness, by increasing levels of G-actin, but also do so by up-regulating TB4.

Additionally, the restriction is improper because examination of groups A and B, and even more so groups A1-A25, would not require additional searches or otherwise place a serious burden on the PTO. MPEP 803 recites that, if "the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."

For these reasons, the examiner is asked to reconsider his position and to withdraw the restriction requirement, in order that the Group A and Group B can be examined as one invention. At the very least, applicants request that groups A2, A3, A7-23 and A25 be examined as one invention. In any event, applicants reserve the right to file a divisional application directed to non-elected claims.

Applicants await examination on the merits. Should there be any questions, Examiner Priebe is invited to contact the undersigned at the number listed below.

Respectfully submitted,

Date 25 October 2002 By S. A. Bent

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